DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2014

Spinal Elements, Incorporated
Mr. Jason Blain
President
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K141372
Trade/Device Name: Mercury® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. Blain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141372

Device Name
Mercury® Spinal System

Indications for Use *(Describe)*
The Mercury® Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/anterolateral nonpedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with bone graft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Mercury® Spinal System

510(k) Number K141372

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
3115 Melrose Dr., Suite 200
Carlsbad, CA 92010
760-607-0121

Contact Information:
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Date Prepared: August 20, 2014

Proprietary Name	Mercury® Spinal System
Device Classification	Spinal Interlaminal Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw System (per 21 CFR Section 888.3050, 888.3060 and/or 888.3070)
Proposed Regulatory Class	Class III
Device Product Code	NKB, MNI, MNH, KWP, KWQ

Purpose of this 510(k)

This 510(k) seeks clearance for line additions to the Mercury® Spinal System previously cleared for use under K071914, K082353, K083230, and K091587. Additionally, the Indications for Use are being modified.

Device Description

Spinal Elements' Mercury Spinal System is comprised of a variety of screws, hooks, rods, connectors, and staples that are used for attachment to the non-cervical spine (the thoracic spine through the sacrum and in the ilium). A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient. Rods span the distance between screws and hooks and achieve fixation by the mechanical joining of the rods with the screws or hooks. Connectors are used to mechanically join one rod to another. Staples (when used) are placed under the head of the screws to help distribute loads placed against the bone.

Screws, hooks, rods, connectors, and staples are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 and ISO 5832-3 or ASTM F 1472. Additionally, some rods may be manufactured from cobalt chromium alloy (Co-Cr) conforming to ASTM F 1537 and ISO 5832-12.

Indications for Use

The Mercury Spinal System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

This system is intended to be used with bone graft.

Substantial Equivalence

The subject Mercury devices are substantially equivalent in indications for use, surgical technique, design features and instrumentation to the following predicate devices:

- Spinal Elements' Mercury Spinal System (K071914, K083230, K082353, and K091587)
- Depuy Acromed's Mossi Miami Spinal System (K030383)
- Synthes' USS Iliosacral System (K082572)

Performance Data

Performance testing included:

- Static Axial Grip and Torsional Grip Interconnection Testing per ASTM F 1798
- Static Compression, Static Torsion, and Dynamic Compression Construct Testing per ASTM F 1717

All data indicates that the device will perform as intended.